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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,419	07/19/2001	Abdul Malik	0152.00396	6244

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EXAMINER	
SODERQUIST, ARLEN	
ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 01/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/763,419	MALIK ET AL.	
	Examiner	Art Unit	
	Arlen Soderquist	1743	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 October 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 8-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 8-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

2. Claims 1-6 and 8-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang or Hayes in view of Ogden or Sumpter (last two newly cited and applied).

The Wang paper has an authorship that is different from the instant inventorship. In the paper Wang teaches sol-gel column technology for single-step deactivation, coating, and stationary-phase immobilization in high-resolution capillary gas chromatography. A sol-gel chemistry-based novel approach to column technology for high-resolution capillary gas chromatography is described that effectively combines surface treatment, deactivation, coating, and stationary phase immobilization into a single step. In the conventional approach, these operations are carried out in separate steps that make column fabrication a time-consuming job. In the taught approach, a cleaned fused silica capillary is filled with a sol solution of appropriate composition, and sol-gel reactions are allowed to go on inside the capillary for a controlled period, typically 15-60 min. A wall-bonded coating results due to condensation of the surface silanol groups with the sol-gel network evolving in their vicinity. Because of the direct chemical bonding to fused silica substrates, sol-gel coatings possess significantly higher thermal stability than conventional coatings. This is especially important for thick and/or polar stationary phase coatings that are difficult to immobilize. Scanning electron microscopic studies revealed that sol-gel coatings were characterized by roughened surfaces, providing a number of chromatographic advantages, including higher surface area and faster mass transfer kinetics.

Sol-gel column technology does not require any free radical crosslinking procedures for stationary phase immobilization and easily avoids any undesirable changes in the stationary phase properties that might be associated with the crosslinking reactions used in conventional technology. Sol-gel-coated poly(dimethylsiloxane) and Ucon columns provided efficient separations for analytes from a wide polarity range, including free fatty acids, phenolic compounds, amines, aldehydes, ketones, alcohols, and diols that are prone to peak tailing due to adsorptive interactions with the column walls. This suggests excellent quality of column deactivation. The technology provided at least a 10-fold reduction in column preparation time. The sol-gel approach is universal in nature and can be effectively applied to a wide range of microcolumn separation techniques. The experimental section of Wang is identical or equivalent to page 20, line 1 to page 26, line, 2 of the instant specification. Also figures 1-2 of Wang are identical to figures 4-5 of the instant specification. In the paragraph bridging pages 4566 and 4567 Wang discusses the criticality of the deactivation step and notes that fused silica capillaries from different batches may not produce identical surface characteristics due to differences in their silanol content based on storage and handling conditions which causes problems with deactivation reproducibility. Wang teaches that others (Sumpter cited, reference 15) have used hydrothermal treatments to standardize the silanol concentration and distributions over the capillary surface. Wang elected not to do a hydrothermal treatment because of the added time to the column making procedure.

The Hayes reference teaches sol-gel chemistry-based Ucon-coated columns for capillary electrophoresis. A sol-gel chemistry-based novel approach for the preparation of a Ucon-coated fused-silica capillary column in capillary electrophoresis is presented. In this approach the sol-gel process is carried out inside 25 □m I.D. fused-silica capillaries. The sol solution contained appropriate quantities of an alkoxide-based sol-gel precursor, a polymeric coating material (Ucon), a crosslinking reagent, a surface derivatizing reagent, controlled amounts of water and a catalyst dissolved in a suitable solvent system. The coating procedure involves filling a capillary with the sol solution and allowing the sol-gel process to proceed for an optimum period. Hydrolysis of the alkoxide precursor and polycondensation of the hydrolyzed products with the surface silanol groups and the hydroxy-terminated Ucon molecules lead to the formation of a surface-bonded sol-gel coating on the inner walls of the capillary. The thickness of the coated

film can be controlled by varying the reaction time, coating solution composition and experimental conditions. Commercial availability of high purity sol-gel precursors (e.g., TEOS 99.999%), the ease of coating, run-to-run and column-to-column reproducibility, and long column lifetimes make sol-gel coating chemistry very much suitable for being applied in analytical microseparations column technology. Test samples of basic proteins and nucleotides were used to evaluate the column performance. These results show that the sol-gel coating scheme has allowed for the generation of biocompatible surfaces characterized by high separation efficiencies in CE. For different types of solutes, the sol-gel coated Ucon column consistently provided migration time R.S.D. values of the order of 0.5%. The experimental section of Hayes is identical or equivalent to page 22, lines 8-24 of the instant specification. Also figure 1 of Hayes is identical to figure 3 of the instant specification. Hayes does not teach a hydrothermal treatment.

In the abstract Ogden discusses characterization of fused-silica capillary tubing by contact angle measurements. The capillary rise method was used to obtain angle measurements on untreated fused silica and fused silica treated with a variety of deactivating reagents. The contact angle data were used in the construction of Zisman plots which allowed characterization of the wettability of the surfaces by their critical surface energies. The wettability of raw fused silica was found to be widely variable which adversely affects attempts to fully deactivate the surface. **Hydrothermal** treatment of the fused silica with HNO_3 was found to be adequate for cleaning and hydroxylating the surface so as to allow complete deactivation. Simple silylating reagents, cyclic siloxanes, and polysiloxanes covering a wide range of polarity were used and evaluated as deactivating reagents.

In the paper Sumpter discusses static coating of 5 to 50 μm I.D. capillary columns for open tubular column chromatography. Dichlorofluoromethane, CCl3F, and Me4Si were used in the static coating of small diameter capillary columns (5 to 50 μm I.D.) to obtain highly efficient columns for gas and supercritical fluid chromatography. Capillary columns of 5-, 10-, 25-, and 50-μm I.D. were coated with stationary phase films of SE-33, SE-54, OV-215, 50% octyl, 45% phenoxypolyethyl ether, 50% liquid crystal, 25% biphenyl, 50% pentafluorophenyl, and 50% cyanopropyl polysiloxane stationary phases. Resultant evaluations of these columns in gas chromatography gave ~9000, 66000, 45000, and 19000 plates m^{-1}, respectively, for the different

internal diameters. Important parameters which affect coating efficiency are identified and discussed in detail. Page 506 teaches treating the columns prior to deactivation by a hydrothermal treatment and a dehydration treatment.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the hydrothermal treatment of Ogden or Sumpter into the methods of Wang or Hayes because of the recognized problem in surface coverage during the deactiviation step and the ability of the hydrothermal treatment to standardize the silanol concentration and distribution as taught by Wang for the Sumpter hydrothermal treatment and allow complete deactivation of the surface as taught by Ogden.

3. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection. The newly cited and applied Ogden and Sumpter references clearly show that hydrothermal treatment of capillary interiors was known prior to the instant invention and was used to overcome the variability of the fused silica that caused problems with the application of a deactivation reagent.

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The additionally cited references are related to column preparation methods and columns made thereby.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arlen Soderquist whose telephone number is (571) 272-1265. The examiner's schedule is variable between the hours of about 5:30 AM to about 5:00 PM on Monday through Thursday and alternate Fridays.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Arlen Soderquist

December 24, 2003

ARLEN SODERQUIST
PRIMARY EXAMINER